DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

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DEC 20 1985

Re: Novafil (4,224,946)
Docket No. 85E-0550
Novafil (4,246,904)
Docket No. 85E-0551

Mr. Charles E. Van Horn
Director, Group 120
U.S. Patent and Trademark Office
Washington, DC 20231

Dear Mr. Van Horn:

This is in regard to the two applications for patent extension for U.S. Patents No. 4,224,946 and No. 4,246,904, filed by American Cyanimid Co. under Title II of Public Law 98-417, 35 U.S.C. 156. The medical device allegedly claimed by the patents is Novafil, premarket application (PMA) number P84-0041.

A review of the Food and Drug Administration's official records corroborates that Novafil, the product identified in the patent extension application, was subject to a regulatory review period before its commercial marketing or use as required by 35 U.S.C. 156(a)(4). Furthermore, our review indicates that PMA No. P84-0041 represents the first permitted commercial marketing or use of this product under section 515(d) of the Federal Food, Drug, and Cosmetic Act. FDA approved Novafil on September 30, 1985 for use in all types of soft tissue approximation, including use in cardiovascular and ophthalmic surgery, but not in microsurgery and neural tissue.

Should you conclude that the subject patent is eligible for patent extension and a determination of the applicable regulatory review period is thus necessary, please advise us. As required by 35 U.S.C. 156(d)(2)(A), we will then determine the regulatory review period, publish that determination in the Federal Register, and notify you of our determination.

Please let me know if we can provide further assistance.

Sincerely yours,

Ronald L. Wilson

Ronald L. Wilson
Director
Health Assessment Policy Staff
Office of Health Affairs

cc: Mr. John J. Hagan
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